



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-276, CMS-1957, CMS-10599 and CMS-10600]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **Insert date 60 days after date of publication in the Federal Register**:

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-276 Prepaid Health Plan Cost Report

CMS-1957 Social Security Office (SSO) Report of State Buy-in Problem

CMS-10599 Medicare Prior Authorization of Home Health Services Demonstration

CMS-10600 Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

1. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Prepaid Health Plan Cost Report; Use: Health Maintenance Organizations and Competitive Medical Plans (HMO/CMPs) contracting with the Secretary under Section 1876 of the Social Security Act are required to submit a budget and enrollment forecast, semi-annual interim report, 4th Quarter interim report, and a final certified cost report in accordance with 42 CFR 417.572 – 417.576. Health Care Prepayment Plans (HCPPs) contracting with the Secretary under Section 1833 of the Social Security Act are required to submit a budget and enrollment forecast, semi-annual interim report, and final cost report in accordance with 42 CFR 417.808 and 42 CFR 417.810. Form Number: CMS-276 (OMB control number 0938-0165); Frequency: Quarterly; Affected Public: Private Sector (Business or other for-profits); Number of Respondents: 91; Total Annual Responses: 74; Total Annual Hours: 3728. (For policy questions regarding this collection

contact Bilal Farrakh at 410-786-4456.)

2. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: Social Security Office (SSO) Report of State Buy-in Problem; Use: Under Section 1843 of the Social Security Act, States may enter into an agreement with the Department of Health and Human Services to enroll eligible individuals in Medicare and pay their premiums. The purpose of the State Buy-in' program is to assure that Medicaid is the payer of last resort by permitting a State to provide Medicare protection to certain groups of needy individuals, as part of the State's total assistance plan. State Buy-in also has the effect of transferring some medical costs for this population from the Medicaid program, which is partially State funded to the Medicare program, which is funded by the federal government and individual premiums. Generally, the States Buy-in for individuals who meet the eligibility requirements for Medicare and are cash recipients or deemed cash recipients or categorically needy under Medicaid. In some cases, States may also include individuals who are not cash assistance recipients under the Medical Assistance Only group. The day-to-day operations of the State Buy-in program is accomplished through an automated data exchange process. The automated data exchange process is used to exchange Medicare and Buy-in entitlement information between the Social Security District Offices, Medicaid State Agencies and the Centers for Medicare & Medicaid Services. When problems arise however that cannot be resolved through the normal data exchange process, clerical actions are required. The CMS-1957, "SSO Report of State Buy-In Problem" is used to report Buy-in problems cases. The CMS-1957 is the only standardized form available for communications between the aforementioned agencies for the resolution of beneficiary complaints and inquiries regarding State Buy-in eligibility. Form Number: CMS-1957 (OMB control number: 0938-0035); Frequency: Reporting – Annually; Affected Public: Individuals and Households; Number of Respondents: 3,936; Total Annual

Responses: 3,936; Total Annual Hours: 1,311. (For policy questions regarding this collection contact Keith Robinson at 410-786-1148.)

3. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicare Prior Authorization of Home Health Services Demonstration; Use: Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)) authorizes the Secretary to “develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act).” In accordance with this authority, we seek to develop and implement a Medicare demonstration project, which we believe will help assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring among HHAs providing services to Medicare beneficiaries.

This demonstration would help assure that payments for home health services are appropriate before the claims are paid, thereby preventing fraud, waste, and abuse. As part of this demonstration, we propose performing prior authorization before processing claims for home health services in: Florida, Texas, Illinois, Michigan, and Massachusetts. We would establish a prior authorization procedure that is similar to the Prior Authorization of Power Mobility Device (PMD) Demonstration, which was implemented by CMS in 2012. This demonstration would also follow and adopt prior authorization processes that currently exist in other health care programs such as TRICARE, certain state Medicaid programs, and in private insurance.

The information required under this collection is requested by Medicare contractors to determine proper payment or if there is a suspicion of fraud. Medicare contractors will request the information from HHA providers submitting claims for payment from the Medicare program in advance to determine appropriate payment. Form Number: CMS-10599 (OMB control number:

0938-NEW); Frequency: Occasionally; Affected Public: Private sector (Business or other for-profits and Not-for-profits); Number of Respondents: 908,740; Number of Responses: 908,740; Total Annual Hours: 454,370. (For questions regarding this collection contact Carla David (410)786-4799.)

4. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration; Use: Primary Immune Deficiency Diseases (PIDD) are caused by genetic defects that result in a lack of and/or impaired antibody function. Without antibodies, the body's immune system is not able to function effectively. Immunoglobulin (IG) therapy is used to temporarily replace some of the antibodies (immunoglobulins) that are missing or not working properly in people with PIDD.

By special statutory provision, Medicare Part B covers intravenous immunoglobulin (IVIG) for persons with PIDD who wish to receive the drug in-home, but does not allow for Medicare to cover any of the items and services needed to administer the drug unless the person is homebound or otherwise receiving services under a Medicare home health episode of care. Therefore, most beneficiaries with PIDD receive treatment at hospital outpatient departments, physicians' offices, and other outpatient settings. A current alternative to IVIG is subcutaneous immunoglobulin (SCIG), a product that permits some beneficiaries to self-administer the immunoglobulin (IG) safely at home without an attending healthcare professional. SCIG at home is reimbursed by Medicare. However, there are limitations to SCIG—e.g., the need for more frequent administration and higher volumes of solution, which can reach a maximum absorbable level for some patients that is below their optimum IG treatment level—that inhibit more widespread use of SCIG.

Under the Medicare Patient IVIG Access Demonstration project, by paying for the items and services needed to administer the IVIG drug in-home, Medicare will enable beneficiaries and their physicians to have greater flexibility in choosing the option that is most appropriate for the beneficiary. With the exception of coverage of these items and services, no other aspects of Medicare coverage for IVIG (e.g., drugs approved for coverage or PIDD diagnoses covered) will change under the demonstration.

The Medicare Patient IVIG Access Demonstration project mandates CMS to:

- Evaluate the impact of the Medicare IVIG Access Demonstration project on Medicare beneficiary access to IVIG at home,
- Determine the appropriateness of implementing a new payment methodology for IVIG in all settings and determining an appropriate payment amount, and
- Update the existing 2007 Office of the Assistant Secretary for Planning and Evaluation (ASPE) report *Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)* (2007 ASPE Report).

The impact evaluation seeks to understand the experiences of demonstration participants and non-participants, to update the 2007 ASPE report, and to support the payment methodology through the use of qualitative and quantitative data collection. The qualitative data collection will consist of a series of stakeholder interviews. Interviews with IVIG/SCIG physicians and nurses will provide information on the experiences of beneficiaries from the perspective of those who have significant, in-depth and practical hands-on experience with delivering IG to Medicare beneficiaries with and without access to home infusions. We will be able to gather their knowledge of beneficiaries' experiences with the care, as well as information on any potential health consequences due to changes in IG medication or participation in the Demonstration. Lastly, we will gather the physicians and nurses' views of the degree to which beneficiaries believe the program is effective, including the cost effectiveness for beneficiaries who use the services

provided under the Demonstration. Form Number: CMS–10600 (OMB control number: 0938–NEW);
Frequency: Annually; Affected Public: Individuals and Households; State, Local or Tribal Governments;
Private Sector (Business or other for-profit); Number of Respondents: 2,488; Total Annual Responses:
2,488; Total Annual Hours: 483. (For policy questions regarding this collection contact Pauline Karikari-
Martin at 410-786-1040).

Dated: February 5, 2016.

William N. Parham, III

Director, Paperwork Reduction Staff

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

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